EXTERNAL FIXATION SYSTEM

Field of the Invention

This invention relates generally to methods, systems and devices for orthopedic external fixation and more particularly to an external fixation system having an improved fixation component for constructing a stable, adjustable fixation system that cooperates with other systems, and methods of use thereof.

Background

Surgeons use external fixation systems regularly to treat certain bony skeletal injuries or conditions, such as acute fractures of the skeleton, soft tissue injuries, delayed union of the skeleton when bones are slow to heal, nonunion of the skeleton when bones have not healed, malunion of broken or fractured bones, congenital deformities resulting in malposition of bone, and bone lengthening, widening, or twisting. Treatment of these conditions often includes stabilization and reduction using an external fixation system. These systems may include a frame comprised of one or more of fixation components and one or more fixation elements. As used herein, fixation component refers to a device for positioning one or more parts of an external fixation system, and fixation element refers to one or more of a bar, rod, wire or pin used in an external fixation system. Wires may be threaded, beaded, or smooth, and pins may be threaded or smooth. Generally, one or more bone pins or wires are inserted into the tissue and bone and then the remainder of the fixation

system is assembled. It is often important that a surgeon is able to place the external fixation system on the patient and then reduce the fracture in an expedited manner. Fracture patterns are infinite and may require the fixation system to move in multiple planes simultaneously in order to stabilize and reduce the fracture properly.

Current external fixation system designs vary, but generally include a mechanism for attaching at least one fixation element to a fixation component to form a construct, or frame, to support a fracture. In general, at least one pin or wire is drilled into the bone. Bone pins typically have one end that is either or both self-drilling and self-tapping, and have a diameter sufficient to resist bending. Bone wires are generally smaller in diameter. Bone pins or wires may be drilled completely through the bone, exiting the skin on the opposite side of the bone, called "transfixation pins," or may extend through the bony skeleton and out only one side of the limb, called "half pins." Current fixation components generally either connect a bar to a bar, a bar to a wire, or a bar to a pin. The frame of an external fixation system may include unilateral bars, which extend along the side of a patient's body, or circumferential or half rings, which encircle a patient's body member entirely or in part. Systems designed to use a circumferential ring or half ring include the ILIZAROV® brand system and the SPATIAL FRAME® brand system. The SPATIAL FRAME® brand system is described in U.S. Patent No. 5,702,389, which is hereby incorporated by reference. Generally, circumferential and half rings have a rectangular cross-section.

When stabilizing and reducing a fracture using an external fixation system, it is important to properly align the bone fragments. Such alignment requires a fixation component that securely joins the pins and wires to the bars, but that is readily adjustable. In many cases, two pins are inserted below the fracture and two pins are inserted above the fracture. The surgeon then attaches a fixation component to each pin, bridging the fixation components together with rods, or bars. These bars form the frame of the external fixation system. As additional fixation components are added to the system in different planes, the frame become less adjustable. Current fixation systems permit a surgeon to choose the positioning of only two fixation components because after placement of two components, additional fixation components will only fit into set positions. During a procedure, it is often necessary to further reduce a fracture, which requires removal of the bars (and loss of positioning) and then replacement of the bars in the frame. Thus, additional reduction is difficult to achieve and requires reestablishment of optional position. Current systems are also highly dependent on accurate pin or wire placement. For example, if the pins or wires are angled incorrectly, the frame cannot be properly constructed

One current external fixation component design includes two clamps that rotate in one plane to allow limited manipulation of the external fixation component. One jaw of each clamp of this design includes a toothed chip mechanism that has a surface with teeth similar to a poker chip. The teeth mate and lock when compressed, and thereby resist rotation in one plane after the clamps are in place. This poker chip design requires that the two fixation elements retained by the component are parallel

to each other in at least one plane that is parallel to the poker chip surface, so that the angular relationship between the two fixation elements is always zero in that plane. Therefore, this system requires a parallel plane between the pin or wire and bar (or between two bars) for each fixation component. This requirement limits the system, as the positioning of each clamp is inhibited. Similar to other current designs, this design becomes substandard when several fixation components are used because it becomes constrained. In addition, the clamps of many current designs are adjacent a central shaft and are both locked upon tightening of a single screw, further constraining the system. Many current designs also allow for placement of the pins in the pin clamp of a fixation element only from the side and require a bent bar for placement of the system proximate the patient, if it is necessary to conform the system to the patient's anatomy. In addition, current designs use compression to hold the bar or pin in place, and may allow dislodgement of the pin or bar upon application of a great amount of pressure to the system when being placed.

Other prior art designs include circumferential rings or half rings, such as those in the ILIZAROV® and SPATIAL FRAME® brand systems. These specialized systems are often used for reduction of a fracture of the proximal tibia or distal femur. Generally, wires connected to half rings are used to stabilize a fracture. These specialized systems do not cooperate with general external fixation systems, and must be used separately.

Thus, there is a need for an external fixation system that provides a greater degree of freedom of rotation of the fixation components and therefore a more

flexible frame construct, sequential locking of capture members, allowing greater adjustability, and cooperation with specialized fixation systems.

Summary of the Invention

An external fixation system according to one embodiment of this invention allows manipulation of an external fixation component in any plane independent of the number of fixation components used, which is provided by the ability of the fixation component to rotate in multiple planes. Further, an improved fixation component according to one embodiment of this invention provides an external fixation system that does not bind or become constricted when numerous fixation components are used, providing the surgeon a stable system that is adjustable. One embodiment of a fixation component according to this invention includes two capture members, each adapted to receive a fixation element. The capture members are coupled such that one capture member is capable of rotation in three axes relative to the other capture member and wherein the coupling is adapted to secure the first and second capture members from rotation with a single activation.

One feature of one embodiment of this invention is a fixation component that provides a greater degree of freedom of rotation.

Another feature of one embodiment of this invention is a fixation component that simultaneously locks a capture member to a fixation element and locks the joint between two capture members.

Yet another feature is a fixation component that allows one capture member to be locked to retain a fixation element without forcing the second capture member also to be locked, allowing additional adjustment of position of the second capture member.

Another feature of one embodiment according to this invention is a fixation component having a locking mechanism that is not dislodged by application pressure.

Yet another feature of one embodiment of this invention is a fixation component that cooperates with specialized fixation systems.

Brief Description Of The Drawings

Figure 1 is a perspective view of a fixation component according to one embodiment of this invention.

Figure 2 is an exploded perspective view of the fixation component of Figure 1.

Figure 3 is a perspective view of the fixation component of Figure 1 with a pin and bar inserted.

Figure 4 is a cross-sectional view of the fixation component taken along lines 4-4 in Figure 1.

Figure 5 is a cross-sectional view of the fixation component taken along lines 5-5 in Figure 1.

Figure 6 is an exploded perspective view of the second capture member of Figure 1.

Figure 7 is a perspective view of a fixation component according to an alternative embodiment of this invention.

Figure 8 is an exploded perspective view of the fixation component of Figure 7.

Figure 9 is a perspective view of the fixation component of Figure 7, with bars inserted in the capture members.

Figure 10 is a perspective view of a fixation component according to an alternative embodiment of this invention.

Figure 11 is an exploded perspective view of the fixation component of Figure 10.

Figure 12 is a perspective view of an external fixation system according to one embodiment of this invention.

Figure 13 is an enlarged fragmentary perspective view of selected fixation components of Figure 12.

Detailed Description

Methods, systems and devices according to this invention seek to provide improved external fixation, including an improved fixation component allowing an increase in freedom of rotation, independent locking of capture members, a more stable, yet more flexible frame, and cooperation with specialized fixation systems. External fixation systems according to embodiments of this invention may include fixation components designed to retain one or more fixation elements. In general, the

fixation components either connect a bar to a bar; a bar to a pin; a bar to a wire; or a bar to a circumferential or half ring. Each fixation component generally includes two capture members, and each capture member includes a base and a head.

One embodiment of a fixation component according to this invention includes a first capture member and a second capture member connected by a joint. Each capture member includes a channel, which allows attachment of a fixation element from the side. The first and second capture members are connected by a joint that allows each capture member to rotate with respect to the other capture member. The joint also allows rotation of up to 50° in any plane (25° each way), increasing the degree of freedom of rotation. In one embodiment, angulation is limited to 50° due to profile height constraints. However, in another embodiment more angulation may be provided. Thus, each capture member is provided three axes of rotation relative to the other capture member (e.g., typical "x," "y," and "z" axes). An external fixation system including fixation components according to this invention allows movement of either the bone, or components of the frame, along six separate axes -- a combination of three orthogonal translational axes and three orthogonal rotational axes -- so the system does not become constrained as additional components are added.

In one embodiment according to this invention, a fixation component having a unique joint allows simultaneous locking of one capture member and the joint. In addition, one capture member may be locked in place while the second capture member continues to freely rotate. In this manner, the surgeon is able to lock one

capture member and continue to rotate the second capture member for final positioning. The surgeon is also able to loosen only one capture member to gain additional reduction, if required, without losing placement, as occurs with current systems when additional reduction is required.

Consider one example of systems and devices according to this invention. As shown in Figures 1-6, a bar-to-pin fixation component 20 includes first capture member 24 and second capture member 22. First capture member 24 retains pin 26, while second capture member 22 is configured to retain bar 28, as shown in Figure 3. The base 30 of first capture member 24 includes a groove 32, while the head 34 of first capture member 24 contains a wedge 36 (Figure 4), which together are adapted to retain pin 26. Likewise, the base 38 and the head 40 of second capture member 22 include a groove 42 and a wedge 44, together adapted to retain bar 28. In one embodiment, groove 42 of second capture member 22 has splines 46, which provide rotational stability of bar 28 and penetrate the surface of bar 28 when second capture member 22 is tightened. Alternatively, the second capture member may be adapted to retain a pin and the first capture member may be adapted to retain a bar. In an alternative embodiment, both the first and second capture members are configured to retain a bar, as shown in Figures 7-9 . In another embodiment, one capture member is adapted to retain a wire, while the other capture member is adapted to retain a bar. Additional embodiments are further described below.

As shown in Figure 2, head 34 of first capture member 24 has a recess 48 adapted to receive spring 50, while base 30 of first capture member 24 includes stop

52. First track 54 on each side of head 34 slides in second track 56 on each side of base 30, allowing the head 34 and the base 30 of first capture member 24 to translate with respect to each other. In an alternative embodiment, second track 56 slides in first track 54. In one embodiment, one of first and second tracks 54, 56 is an L-shaped track, while the other track is shaped to receive the L-shaped track. As a force in a direction perpendicular to the pin is exerted against the groove 32 and wedge 36 of the first capture member 24, the head 34 moves, compressing the spring 50 against the extended portion of the base 30. The spring 50 compresses until it exerts a force in a direction perpendicular to the pin 26 that is equal and opposite to the force exerted against the wedge 36. At that point, the head 34 stops moving and holds the pin 26 in the groove 32 and wedge 36, which together form channel 58. After the pin 26 is located in the channel 58, the force of the spring 50 will temporarily hold the pin in position until the angular position of the channel 58 is set by tightening first fastener 60. Base 30 of first capture member 24 includes elevated portion 61, as shown in Figure 4, forcing two points of contact between base 30 and head 34 in order to increase the holding power of first capture member 24. Base 38 of second capture member 22 also includes an elevated portion 63, also shown in Figure 4, which increases the holding power of second capture member 22 in the same manner.

Second capture member 22 includes also includes a cartridge mechanism for retaining a bar 28. Head 40 of second capture member 22 has a recess 62 adapted to receive a spring 64, while base 38 of second capture member 22 includes stop 66. First track 68 on each side of head 40 slides in second track 70 on each side of base

38. In an alternative embodiment, second track 70 slides in first track 68. In one embodiment, one of first and second tracks 68, 70 is an L-shaped track, while the other track is shaped to receive the L-shaped track. Groove 42 and wedge 44 of second capture member form second capture member channel 72, which receives a bar 28. A bar 28 is retained in second capture member 22 in the same manner as first capture member 24 retains a pin 26.

In an alternative embodiment, one or both capture members may include two recesses for receiving two springs and two spring stops. In the embodiments shown, the recess, spring and stop are located on one side of the capture member. In an alternative embodiment, the recess, spring, and spring stop are in the middle of the capture member, or are on the other side of the capture member. In one embodiment, each head 40, 34 of the capture members 22, 24 includes grip surfaces 74, 76 for gripping and sliding heads 40, 34 in relation to bases 38, 30. In one embodiment, grip surfaces 74, 76 include ridges.

Threaded end 78 of first fastener 60 is adjacent a biasing element, such as center spring 80, and passes through keyhole aperture 82 in head 34 of first capture member 24, mating to internal threads 84 in base 30 of first capture member 24. Keyhole aperture 32 of head 34 if first capture member 24 allows reduced diameter neck 85 of first fastener 60 to translate within the aperture 82. Tightening of first fastener 60 locks the first capture member 24 and rigidly retains pin 26. In an alternative embodiment, the aperture 82 is circular, or any other suitable shape.

Connector 86 having end 88 and shaft 90 extends through keyhole aperture 92 in the base 30 of the first capture member 24. In one embodiment, the connector is a ball stud, as shown in Figure 2, having a spherical end. The end 88 of connector 86 is received in planetary member 94 of base 30 of first capture member 24. As used herein, a planetary member refers to an object that is received in another object, and that receives another object within itself. In one embodiment, planetary member 94 is an outer sphere, as shown in the Figures. Shaft 90 of connector 86 extends through aperture 98 in base 38 of second capture member 22 and aperture 98 of head 40 of second capture member 22, and mates with second fastener 100. Threads 102 on shaft 90 of connector 86 mate with internal threads 104 of second fastener 100. Slot 106 in aperture 96 of base 38 of second capture member 22 is adapted to receive key 108 on the shaft 90 of the connector 86. Key 108 and slot 106 thus prevent rotation of the connector 86 within second capture member 22. In another embodiment, any suitable mechanism for preventing rotation of the connector is used. In other words, the connector fits through the base of the first capture member and the end is received in the planetary member of the base, while the shaft of the connector extends through both the base and head of the second capture member and threads to a second fastener. A planetary member, for example outer sphere 94, fits within cooperating surface 110, which is machined into the one side of the base 38 of the second capture member 22. Tightening of the second fastener 100 on the second capture member 22 draws the connector 86 into the planetary member 94, locking the second capture member and the joint to make it rigid. In one embodiment, one or both of the

planetary member and cooperating surface may be tapered. For example, a taper of 10°, 15°, 20° or 30° may be used on each.

The joint mechanism described above allows the second capture member to rotate with respect to the planetary member of the first capture member, and allows the first capture member to grasp and lock a pin while permitting the second capture member to continue to rotate. Independent tightening of the capture members provides the surgeon flexibility to snap a fixation element to a capture member and then to manipulate the second capture member before locking the second capture member in order to achieve a more stable frame. In this manner, independent tightening of each capture member of the external fixation component allows more precise angular positioning.

Other embodiments, such as a bar-to-bar fixation component, shown in Figures 7-9, and a bar-to-wire fixation component, also may contribute to a more stable, more adjustable external fixation system. These embodiments function similarly to the bar-to-pin fixation component, with the capture members having a wedge and groove adapted to form a channel sized for receiving either a bar or a wire, depending on the component.

In one embodiment, a cartridge locking of the pin and bar is provided, as described above. However, in alternative embodiments, other one-piece designs may be used. For example, a solid piece of aluminum metal having the shape of the two part head and base cartridge construct of the two capture members may be used. This one-piece design includes a channel in each one piece capture member and a slot that

extends close to the rear portion of the capture member. The slot causes the material to behave similar to a spring and allows the capture member to open when pressure is placed against it, so that a fixation element may be snapped into place in the channel.

Several mechanisms may be used to improve the locking capabilities of the joint. Coatings or elastic materials or alternate taper shapes may be applied to any of the articulating surfaces. For example, coatings or elastic materials or alternate taper shapes may be applied to one or both of the planetary member and cooperating surface so that a textured surface on either or both improves locking. In one embodiment, the cooperating surface is coated with SC729, a coating manufactured by Hitemco. In this embodiment, the cooperating surface is very rough and is made from tungsten cobalt carbide. In this embodiment, the value for slip increases to about 240 in.-lb., from about 140 in.-lb. without the coating. In an alternative embodiment, a mechanical locking pattern is applied. For example, splines and dimples may be added to one or both of planetary member and cooperating surface, providing teeth to grab when locking, thereby improving the locking function. A 30 degree chosen taper configuration on the inside of the planetary member mating surface uses a taper design to achieve torque strength of up to 200 in.-lb.

In an alternative embodiment, a fixation component is designed for attachment to a circumferential external fixator system, such as an ILIZAROV® brand system, a SPATIAL FRAME® brand system, or other spatial frame, to achieve a hybrid external construct. In this embodiment, shown in Figures 10-11, the fixation component includes a capture member for retaining a bar and a capture member for

retaining a half or circumferential ring having a generally rectangular cross-section. Use of a fixation component having a capture member for retaining a ring allows a surgeon to create a hybrid frame, using both a standard external fixation system and a system that includes a circumferential external frame. This hybrid system is very useful in adapting a system for treating a shaft fracture, or typical in-line fracture, to one for treating a plateau fracture, which is a fracture in a joint space. A T-component 112 according to one embodiment of a fixation component of this invention includes a second capture member 114 that is similar to the second capture member described above with respect to the bar-to-pin fixation component. Head 116 of second capture member 114 has a recess adapted to receive a spring, while base 122 of second capture member 114 includes a stop 124, and functions with recess 118 and spring 120 as described above. Second capture member 114 also includes first tracks 126 and second tracks 128 so that the head 116 and base 122 translate and retain a bar in a groove 130 and wedge 132 in the same manner as described above.

Base 122 of second capture member 114 also includes cooperating surface 134, which is adapted to receive planetary member 136 of first capture member 156. Connector 138, which, as described above and shown in Figure 11, may be a ball stud, has shaft 140 that extends through apertures 142, 144 in the base 122 and head 116 of second capture member 114. Slot 146 in aperture 142 of base 122 is adapted to receive a key 148 on the shaft 140 of the connector 138 in order to prevent rotation of connector 138 within second capture member 114. Threads 150 on shaft 140 mate with second fastener 152, while end 154 is received in planetary member 136.

First capture member 156 includes base 158 and head 160, each having a recess 162, 164, which together form channel 166, adapted to receive a ring having a rectangular cross-section. Head 160 has extension 168 that fits into rim 170 of base 162. Rod 172 includes second threads 174 that mate with the internal threads 176 of aperture 178 of base 158 after extending through aperture 180 of head 160. Biasing element 182, such as a spring, passes over rod 172 and also into aperture 184 of first fastener 186. First threads 188 of rod 172 mate with internal threads 190 of first fastener 186. Tightening of first fastener 186 thus locks the base 158 and head 160 of first capture member 156. Second capture member 114 is free to rotate about planetary member 136 of base 158 of first capture member 156 until second fastener 152 is tightened, at time both the second capture member 114 and the planetary member 136 and cooperating surface 134, which form the joint, are locked.

In an alternative embodiment, other locking mechanisms may be used, such as a universal joint mechanism, which allows independent movement in different directions. In yet another alternative embodiment, the capture member may include a flip through for the bar or pin, rather than a snap-on from the side as described above.

One embodiment of a fixation component of this invention is made from titanium and aluminum. In this embodiment, the heads of the capture members are made from aluminum and the remaining parts from titanium. In alternative embodiments, fixation components are made from metals, alloys, plastics, composites, ceramics, or any other suitable material.

One method of using one form of structure according to this invention, shown in Figure 13, which includes an improved fixation component for achieving optional external fixation of bones, is as follows:

At least two half pins are self-drilled into a bone, one on either side of a bone fracture. One bar-to-pin fixation component is connected to each pin by placing each pin into the capture member of each fixation component sized to receive a pin, such as the first capture member of the bar-to-pin fixation component shown in Figure 1. Each fixation element is placed into the fixation component from the side for easy placement. After a pin is in place, the first fastener is tightened, so that the pin is retained in the capture member, while the second capture member and joint continue to freely rotate. Bars are then snapped into the bar capture member of the fixation components, forming a frame for the system. As each bar is added, the fixation components are adjusted as required by loosening the joint and second capture member, so that optimal positioning may be obtained. Bar-to-bar fixation components and bar-to-pin fixation components may be added to expand and connect the frame as required. If it is necessary or desirable to utilize a circumferential ring or half ring with a system for complex fractures, as shown in Figure 13, additional fixation components having capture members designed to retain the rectangular bar of a ring are used to join the standard system to the specialized frame. A T-component is used to capture the rectangular bar of a ring and link it to a bar of the original frame, forming a hybrid system. If additional reduction is required, one capture member of any component may be loosened without losing placement of the system.

A T-component may also be used to provide stability to an existing system that has already been placed using standard fixation component designs. A plurality of clamps may be used in various configurations to achieve stability for different fractures.

Similar instrumentation and devices may be used in other areas, such as to provide a fixed reference to a pin. Constructs made under the present invention are stable and provide for a wide variety or placements. Embodiments of an external fixation component according to this invention may also be adapted for use with an image guided surgery system to provide stability to a reference frame or other guidance target or mechanism.

As various changes could be made in the above constructions and methods without departing from the scope of the invention as defined in the claims, it is intended that all matter contained in the above description or shown in the accompanying drawings be interpreted as illustrative and not in a limiting sense.